

REMARKS

1. Status of the claims

Claims 2-5 and 7-11 are currently pending. Claims 1, 6 and 12-17 were previously cancelled. Claims 1 and 7-8 are currently amended.

Claim 1 has been amended to remove the recitation of "for immunoglobulin G composition." Support for this deletion can be found in the Specification as filed at, for example, page 5, lines 29-31.

Claim 7 has been amended to remove the term "comprising" and is replaced by the expression "consisting of immunoglobulins G, of water and of." Support for the addition of the term "water" can be found *e.g.* in the Specification as filed at, for example, page 6, lines 2-10.

Claim 8 has been amended to remove the term "comprising" which is replaced by the expression "consisting of immunoglobulins G and of."

No new matter has been added.

2. Claim Rejection under 35 U.S.C. § 112 second paragraph

Claims 2 to 5 are rejected by the Examiner under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject-matter which Applicant regards as the invention.

Applicant submits that claim 2 as amended such is clear that the subject-matter of the claim is directed to a stabilizing formulation solely, consisting of a sugar-alcohol, glycine and a non-ionic detergent. The stabilizing formulation once prepared may be added to immunoglobulins G (IgG) in order to stabilize them under liquid and/or lyophilized forms (see the Specification as filed, example 1 at page 8, lines 19-22). Such a stabilized formulation is now recited in claim 8.

Accordingly, withdrawal of the corresponding rejection is respectfully requested.

3. Claim Rejection under 37 C.F.R. § 1.75 (c)

Claims 7 to 11 are rejected by the Examiner under 37 C.F.R. § 1.75 (c) as being improper dependent from for failing to further limit the subject-matter of a previous claim.

Applicant submits that claim 7, as presently amended, now recites an IgG composition which is specifically limited to IgG, water, a sugar-alcohol, glycine and a non-ionic detergent. Claim 7 is indeed now drafted with the expression "consisting of." The same applies to claim 8 for which the subject-matter is now limited to an IgG composition in a lyophilized form consisting of IgG, of a sugar alcohol, of glycine and of a non-ionic detergent. Applicant asserts that claims 7 to 11 include all of the limitations of claim 2, and should therefore be considered as dependent claims thereof.

Accordingly, withdrawal of the rejection is respectfully requested.

4. Claim Rejection under 35 U.S.C. 102 (b) (see paragraph 5 of the Office Action)

According to the Office Action dated December 16, 2010, novelty of claims 2 to 5 as previously presented is acknowledged by the Examiner (see paragraph 2 of the Office Action).

Claims 7 to 11 are nevertheless rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,945,098. Without endorsing this assertion, Applicant will now focus on demonstrating that claims 7 to 11 as presently amended are novel over U.S. Patent No. 5,945,098.

First of all, Applicant submits that claims 7 and 8, as amended, now recite an IgG composition consisting of IgG, water and the stabilizing formulation according to claim 2.

U.S. Patent No. 5,945,098 discloses an IgG preparation comprising an aqueous solution of Ig, an amino acid (*e.g.* glycine) and a non-ionic detergent (*e.g.* Tween™ 80) (see column 3, lines 42-50 and column 4, lines 57-59). U.S. Patent No. 5,945,098 further discloses Ig preparations comprising an aqueous solution of Ig, a polyvinylpyrrolidone (PVP), a non-ionic detergent and a compound selected from the group consisting of carbohydrates (*e.g.* mannitol; see column 5, lines 38-41), of physiologically acceptable salts and of amino acids (see column 3, lines 51-61). The Ig preparation disclosed in U.S. Patent No. 5,945,098 is intended to provide a storage-stable liquid product (see column 3, last paragraph).

U.S. Patent No. 5,945,098 nevertheless fails to disclose any IgG preparation consisting solely of IgG, of a sugar alcohol, of glycine and of a non-ionic detergent. In U.S. Patent No. 5,945,098, the only IgG preparation comprising IgG, a sugar alcohol (mannitol), glycine and a

non-ionic detergent (Tween™ 80) indeed further includes residual amount of polyethylene glycol (PEG) (see column 7, example V). Moreover, the Ig preparations disclosed in U.S. Patent No. 5,945,098 are under liquid form only (see column 2, lines 35-38; see also column 3, lines 62-64), and U.S. Patent No. 5,945,098 therefore fails to disclose any Ig preparation under a lyophilized form. Considering that the IgG composition of the present invention specifically excludes the presence of other stabilizers such as polyethylene glycol (PEG), claims 7 to 11 as presently amended are therefore novel over U.S. Patent No. 5,945,098.

Accordingly, Applicant requests withdrawal of the rejection.

5. Claim Rejection under 35 U.S.C. 103 (a) (see paragraph 7 of the Office Action)

According to the Office Action dated December 16, 2010, inventive step of claims 2 to 5 as previously presented is acknowledged by the Examiner (see paragraph 7 of the Office Action, page 5).

Claims 7 to 11 are nevertheless rejected by the Examiner under 35 U.S.C. § 103 (a) as being unpatentable U.S. Patent No. 4,597,966, in view of EP 0,392,717 and of U.S. Pub. No. 2006/0246060.

The Examiner considers in particular that U.S. Patent No. 4,597,966 teaches a stabilized IgG preparation comprising IgG, histidine and glycine at a concentration of about 0.1 M, and that it would have been obvious for the skilled person in the art to add a sugar-alcohol such as mannitol at the concentration as taught in EP 0,392,717, and a non-ionic detergent as taught in U.S. Pub. No. 2006/0246060 to the IgG preparation taught in U.S. Patent No. 4,597,966 for obtaining the IgG composition of the present invention.

Applicant respectfully disagrees for the following reasons.

First of all, attention of the Examiner is drawn to the fact that claims of the present application were amended to recite an IgG composition consisting of IgG, of a sugar-alcohol, of glycine and of a non-ionic detergent, and further consisting of water when said composition is under liquid form.

U.S. Patent No. 4,597,966 teaches a stabilized Ig preparation comprising IgG, histidine and glycine (see column 4, lines 30-37). The Ig preparation taught by U.S. Patent No. 4,597,966

may further comprise thimerosal (see column 8, line 42) and sodium chloride (see column 10, table II, lines 3-5). U.S. Patent No. 4,597,966 nevertheless fails to teach or even suggest the addition of a sugar-alcohol and of a non-ionic detergent to the disclosed preparation.

EP 0,392,717 teaches an Ig preparation comprising Ig in association with stabilizing amounts of glycine and of mannitol (see abstract). EP 0,392,717 nevertheless fails to teach any Ig preparation containing a non-ionic detergent.

U.S. Pub. No. 2006/0246060 teaches a stable formulation for an Ig conjugate (HuC242-DM1, which is an antibody conjugated to a cytotoxic agent; see paragraphs [0001] and [0004]), as well as a stable formulation for an antibody (C242, which is a humanized monoclonal antibody; see paragraphs [0005] and [0015]). The stable formulation taught by U.S. Pub. No. 2006/0246060 comprises the antibody in a buffer controlling the pH value of solution, and containing sucrose or trehalose (see paragraphs [0004], [0005] and [0022]). The disclosed formulation may further comprise a non-ionic detergent (see paragraph [0021]). U.S. Pub. No. 2006/0246060 nevertheless fails to teach or even suggest any Ig preparation containing a sugar-alcohol and glycine.

In view of the combined teachings of U.S. Patent No. 4,597,966, of EP 0,392,717 and of U.S. Pub. No. 2006/0246060, the person of ordinary skill in the art would not have been motivated to prepare an IgG composition comprising IgG, mannitol, glycine and a non-ionic detergent. It must further be acknowledged that the person skilled in the art would never have had any reasonable expectation of success to prepare an IgG composition solely consisting of IgG, of glycine, of a sugar-alcohol and of a non-ionic detergent (including water when the composition is under liquid form).

Indeed, U.S. Patent No. 4,597,966 teaches that the solubility of Ig is influenced by the pH of the system in which the protein is present, and that Ig are stabilized against aggregation by maintaining the solution pH at a slightly acidic value (see column 4, lines 48-61 and lines 11-17). U.S. Patent No. 4,597,966 teaches in particular that the ability of the disclosed preparation to maintain the solution pH at a slightly acidic value is due to the presence of histidine (see column 5, lines 39-42). U.S. Patent No. 4,597,966 also teaches that histidine is preferably used together with glycine (see column 4, lines 63-64). Moreover, U.S. Patent No. 4,597,966 teaches that a

formulation consisting solely of a glycine-saline buffer is insufficient for controlling the pH value of a gamma globulin solution which has a relatively low protein concentration (see column 3, lines 52-64; see also column 10, lines 54-57 and column 11, lines 32-36). In view of the teaching of U.S. Patent No. 4,597,966, a person skilled in the art would never have had any reasonable expectation or motivation to prepare an IgG preparation which does not contain histidine. On the contrary, in view of the combined teachings of U.S. Patent No. 4,597,966 and of EP 0,392,717, the person skilled in the art would have been motivated to add both histidine and glycine as stabilizing agents in an IgG preparation. Moreover, U.S. Publication No. 2006/0246060 teaches a stable formulation in which sucrose and a pH-buffered solution are systematically incorporated (see paragraphs [0004] and [0005]; see also claim 1). In view the teaching of U.S. Publication No. 2006/0246060, the person skilled in the art would thus never have had any reasonable expectation to prepare an Ig preparation which does not comprise sucrose and a pH-buffered solution.

Therefore, Applicant respectfully submits that in view of the combined teachings of U.S. Patent No. 4,597,966, of EP 0,392,717 and of U.S. Patent No. 4,597,966, the person of ordinary skill in the art would have had no reasonable expectation of success to prepare an Ig preparation consisting only of Ig, a sugar-alcohol, glycine and a non-ionic detergent.

In view of the above, the subject-matter of claims 7 and 8 as well as that of claims 9 to 11 is thus non-obvious over the teachings of U.S. Patent No. 4,597,966, EP 0,392,717 and U.S. Publication No. 2006/0246060, even when combined together.

Accordingly, withdrawal of the rejections is thus respectfully requested.

Applicant believes the pending application claims subject matter free of the prior art and that the application is in condition for allowance. The favorable actions of withdrawal of the pending rejections and allowance of the claims is requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant respectfully petitions for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1,110.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No.

Application No. 10/552,314
Amendment dated June 15, 2011
After Final Office Action of December 13, 2010

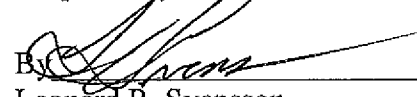
Docket No.: 0040-0158PUS1

30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: June 15, 2011

Respectfully submitted,



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